

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

JAN LEIGH BLOCK, et al.)	
)	
Plaintiffs,)	
)	
v.)	No. 1:19-cv-04546-SEB-TAB
)	
ETHICON, INC., et al.)	
)	
Defendants.)	

**ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS'
MOTION TO EXCLUDE SPECIFIC-CAUSATION TESTIMONY OF
MICHAEL THOMAS MARGOLIS, M.D.**

Now before the Court is Defendants' Motion to Exclude Specific-Causation Testimony of Michael Thomas Margolis, M.D. [Dkt. 86]. Defendants Ethicon, Inc. and Johnson & Johnson move, pursuant to Federal Rules of Evidence 702 and 703 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to exclude Dr. Margolis's specific causation opinions on various grounds. Plaintiffs oppose Defendants' Motion. For the reasons detailed below, we GRANT IN PART and DENY IN PART Defendants' Motion to Exclude.

Factual Background

On March 9, 2007, at the age of 47, Lead Plaintiff Jan Leigh Block was implanted with transvaginal tape ("TVT") by Gregory A. Miller, M.D., to treat her stress urinary incontinence. Ms. Block's TVT procedure was performed in conjunction with a total vaginal hysterectomy and bilateral salpingo-

oophorectomy. She underwent mesh revision procedures in October 2007 and December 2007 before a mesh excision on May 27, 2008. Ms. Block alleges that her TVT caused her dyspareunia, urinary tract infections, pelvic pain, bowel and urinary problems, vaginal scarring, muscle weakness, vaginal burning sensation, and mental and emotional distress.

The opinion testimony of Dr. Margolis, a pelvic surgeon and urogynecologist, is the subject of this motion. Dr. Margolis is one of a small group of American physicians who are board-certified in the obstetrics and gynecology subspecialty of Female Pelvic Medicine and Reconstructive Surgery. He has observed numerous sling and mesh procedures involving the TVT and has studied related textbooks, publications, instructions for use ("IFU"), surgical videos, cadaver dissections, and operative reports. Dr. Margolis has also personally performed the explantings of over 300 mesh slings and devices, including the TVT device.

Plaintiffs have designated Dr. Margolis as their case-specific expert regarding injuries caused by the implantation of Ethicon's Gynecare TVT device. Dr. Margolis's findings and opinions on the cause of Mrs. Block's injuries and the inadequacy of Defendants' IFU are set forth in his four expert reports, dated July 26, 2017, July 27, 2017, October 3, 2017, and October 25, 2017, respectively.

Legal Analysis

I. Applicable Standard

The admissibility of expert testimony is governed by the analytical framework set out in Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993). *Lewi v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). To be admissible under Rule 702 and *Daubert*, an expert's testimony must be reliable and relevant, and the expert must be qualified to give it. Fed. R. Civ. P. 702; *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010). If the *Daubert* threshold is cleared, "the accuracy of the actual evidence is to be tested before the jury with the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012) (quoted with unmarked alterations *Daubert*, 509 U.S. at 596). The proponent of expert testimony bears the burden of establishing admissibility by a preponderance of the evidence. *Lewis*, 561 F.3d at 705.

II. Discussion

Defendants seek to exclude the following expert testimony by Dr. Margolis: his specific causation testimony, his opinions as to Mrs. Block's prognosis, his testimony regarding the adequacy of the TVT's IFU, his opinions regarding the state of mind of Defendants and Mrs. Block's physician, any testimony regarding

medical conditions or characteristics not identified in Mrs. Block's medical records, and, finally, any opinions not included in his expert reports. We address each of these arguments in turn below.

A. Specific Causation Opinions

1. Qualifications

As detailed above, Dr. Margolis is a pelvic floor surgeon and urogynecologist with extensive experience implanting and removing sling systems. *See In re Ethicon, Inc.*, Master File No. 2:12-MD-02327, MDL No. 2327, 2014 WL 186872, at *17 (S.D.W.Va. Jan. 15, 2014). He is also one of a small group of American physicians who are board certified in the obstetrics and gynecology subspecialty of Female Pelvic Medicine and Reconstructive surgery. His qualifications and experience in the areas of the effectiveness of Defendants' TVT product as well as mesh reaction and its effect on the human body have been acknowledged in prior TVT litigation and we do not understand Defendants to challenge those qualifications here. Accordingly, we find that Dr. Margolis is qualified to offer the opinions on specific causation set forth in his report.

2. Reliability

Defendants seek the exclusion of Dr. Margolis's specific causation opinions on grounds that he fails to identify a reliable and trustworthy basis for those opinions. However, it is within Dr. Margolis's knowledge and expertise to testify

regarding the particular features of Defendants' TVT product that he finds problematic, including small pore size, deformed pores, and shrinkage. In reaching his conclusion that Mrs. Block's injuries were caused by these features of Defendants' TVT, Dr. Margolis utilized a technique called differential diagnosis, which "is an accepted and valid methodology for an expert to render an opinion about the identity of a specific ailment." *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). In a differential diagnosis, "the doctor rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013) (quoting *Meyers*, 629 F.3d at 641).

Here, Dr. Margolis performed a reliable differential diagnosis as he reviewed Mrs. Block's medical records and personally examined her to rule out any other potential causes of her symptoms, ultimately concluding that she exhibited no signs or symptoms in any of her medical records of any other conditions that could result in dyspareunia or recurrent urinary tract infections. This methodology passes scrutiny under *Daubert*. While Defendants clearly disagree with Dr. Margolis's testimony, the "soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact" *Smith v. Ford Motor Co.*,

215 F.3d 713, 718 (7th Cir. 2000). Any perceived insufficiencies in Dr. Margolis's testimony can be addressed by Defendants through vigorous cross-examination.

The requested exclusion or limitation of this testimony on the basis of its unreliability is therefore denied.

3. Failure to Rely on General Causation Opinion

Defendants also argue that Dr. Margolis's specific causation opinions should be excluded because he does not rely on any general causation opinions to support his conclusions. It is true that Plaintiffs must show both general and specific causation to prevail on their IPLA claim and that "a jury can't weigh evidence of specific causation until the [plaintiffs] have first proven general causation." *C.W. v. Tectron, Inc.*, No. 3:10 CV 87, 2014 WL 4979211, at *4 (N.D. Ind. Oct. 3, 2014) (citations omitted). Here, however, Dr. Margolis has set forth general causation opinions in his July 26, 2017 report and also indicated in his October 25, 2017 report that he relied on the general causation opinions of Plaintiffs' other experts in reaching the conclusions set forth in his July 26, 2017, July 27, 2017, and October 3, 2017 reports. Dkt. 86-2 at 96 (CM-ECF page number). Accordingly, we deny Defendants' request to exclude Dr. Margolis's testimony on grounds that he failed to rely on any general causation opinion in reaching his specific causation opinion. To the extent Defendants believe the foundation of Dr. Margolis's testimony is lacking, they may, of course, cross-examine him on that issue at trial.

4. Improper Legal Conclusions

Defendants claim that Dr. Margolis's opinions referring to TVT as "defective" or "inadequately designed" or on the basis of other similar legal terms of art should be excluded because the MDL court, when considering an earlier challenge to Dr. Margolis's expert opinion testimony, held that "an expert may not offer expert testimony using 'legal terms of art,' such as 'defective,' 'unreasonably dangerous,' or 'proximate cause.'" *In re: Ethicon, Inc.*, Master File No. 2:12-MD-02327, MDL No. 2327, 2016 WL 4536885, at *4 (S.D.W.Va. Aug. 30, 2016). While we, of course, acknowledge and incorporate here the previous rulings of the MDL court and thus accept Defendants' motion as well-taken insofar as Dr. Margolis's testimony cannot include statements that Defendants' TVT product is "defective," the MDL order does not require the total exclusion of this evidence. Dr. Margolis can, and will be permitted to testify regarding the attributes of Defendants' device that he believes caused Mrs. Block's injuries, but must stop short of labeling them "defects." *Cf. Lancaster v. Ethicon*, 1:19-CV-1377 (LEK/ML), 2020 WL 819291, at *7 (N.D.N.Y. Feb. 19, 2020) ("[T]he Court sees no obstacle to [the expert] attributing [the plaintiff's] injuries to 'features' or 'characteristics' of Defendants' mesh rather than particular 'defects.' In this way, [the expert] could describe what attribute of Defendants' mesh caused [the plaintiff's] injuries without straying toward the proscribed language.").

B. Testimony Regarding Prognosis and Future Treatment

Defendants next argue that Dr. Margolis's opinions regarding Mrs. Block's prognosis and future treatment must be excluded because they are speculative and not supported by scientific analysis or a reliable foundation. Specifically, Dr. Margolis has opined that Mrs. Block's dyspareunia is permanent and that, even if she were to undergo an explant of the entire sling, such a procedure would, at best, merely diminish her pain, not fully resolve it. Dr. Margolis also has stated in his report that a Burch procedure—a surgical procedure used to treat urinary incontinence—would have no more than a 50% to 60% chance of success in resolving Mrs. Block's stress incontinence.

Contrary to Defendants' characterizations of his report, Dr. Margolis references substantial evidence in Mrs. Block's medical records and deposition testimony to support his conclusions regarding the severity of her condition. In addition to these documentary sources, Dr. Margolis personally examined Mrs. Block, noting that the evidence gleaned from her examination corroborates her complaints. Thus, we hold that Dr. Margolis's opinions regarding Mrs. Block's prognosis reflect the results of a reliable methodology, to wit, his extensive experience and relevant medical knowledge in the field of urogynecology as well as a thorough review of her detailed medical history in addition to his own clinical examination of her. Dr. Margolis's opinions as to Mrs. Block's prognosis are

therefore admissible, given the sufficient scientific basis for such testimony. *See In re Yasmin and YAZ (Drospirenone) Marketing, Sales Practices, and Products Liability Litigation*, No. 3:09-md-02100-DRH-PMF, MDL No. 2100, 2011 WL 6733952, at *6 (S.D. Ill. Dec. 16, 2011) ("[A]s [the expert] bases his opinion on a reliable methodology; specifically, his experience and relevant medical knowledge, the Court finds his opinions as to plaintiff's prognosis, including her possible future harm, ... admissible."). Again, Defendants' objections to the admissibility of these opinions goes to their weight, and can be addressed on cross-examination.

C. Testimony Regarding the Adequacy of Warnings

Defendants also seek to exclude any testimony from Dr. Margolis regarding the adequacy of the warnings included on the TVT's IFU on grounds that he is not qualified to offer such opinions. Defendants claim that, even if he were qualified to testify on this subject, Dr. Margolis's opinions are inadmissible because he fails to identify any reliable data or scientific bases supporting his conclusion that the 19 alleged risks identified in his reports are, in fact, associated with the use of TVT, or that they are statistically significant enough to have affected Mrs. Block's treating physician's medical advice had they been included on the TVT's IFU.

With regard to Dr. Margolis's qualifications to offer opinions as to the adequacy of warnings, the MDL Court has ruled that urogynecologists such as Dr. Margolis may testify "about the specific risks of implanting mesh and whether those risks

appeared on the relevant IFU," but those "same expert[s] must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon, Inc.*, 2016 WL 4536885, at *2 (citation omitted). Here, Plaintiffs have not shown that Dr. Margolis possesses any such additional expertise, education, training, or experience in the area of drafting of IFU warnings. They argue only that Dr. Margolis has reviewed Defendants' corporate documents and the depositions of their corporate designees and "relied on this knowledge, in combination with his specialized experience as a pelvic floor surgeon and urogynecologist who has implanted over 300 mesh devices, and the general body of literature surrounding TVT mesh devices when he formed his opinions about the adequacy of the TVT IFU." Dkt. 86-2 at 17 (CM-ECF page number). None of Dr. Margolis's admittedly extensive experience extends into the field of drafting IFU warnings, however. Without such expertise, he is not qualified to testify regarding what warnings, if any, are required relating to an IFU.

Accordingly, any such testimony from Dr. Margolis is excluded. His testimony on the topic of IFU warnings, accordingly, must be limited to the identification of specific risks associated with mesh implantation and whether such risks appeared on the TVT IFU, topics which are within his knowledge and expertise. Further, Dr. Margolis may testify only as to those risks that are related to symptoms and conditions actually experienced by Mrs. Block. We agree with

Defendants that the relevance, if any, of broader testimony regarding potential risks unrelated to the specific facts of this case is limited, and any probative value is greatly outweighed by potential prejudice and jury confusion. Defendants' remaining objections are overruled because they go to the weight of Dr. Margolis's testimony and can be addressed on cross-examination.

D. Testimony Regarding State of Mind

Defendants next argue that Dr. Margolis should be precluded from testifying as to: (1) the state of mind of Mrs. Block's treating physician, Dr. Miller, or speculating as to how a different IFU would have impacted the surgeon's treatment decisions or informed consent discussions; and (2) Ethicon's corporate conduct, knowledge, state of mind, or alleged bad acts. Plaintiffs have not responded to Defendants' request to exclude state of mind evidence regarding Dr. Miller. Accordingly, that portion of Defendants' motion is granted, and Dr. Margolis is prohibited from testifying as to Dr. Miller's state of mind or speculating as to what information in the IFU would have been important to Dr. Miller in considering treatment options.

With regard to testimony going to the state of mind of either Defendant, Plaintiffs agree not to present testimony explicitly referencing Defendants' state of mind. We agree with Plaintiffs, however, that Dr. Margolis is not precluded entirely from testifying regarding internal corporate documents that he may have

reviewed in forming his opinions. Rather, Dr. Margolis may "testify as to a review of internal corporate documents solely for the purpose of explaining the basis of his ... opinions—assuming the opinions are otherwise admissible" *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liability Litigation*, 948 F. Supp. 2d 589, 611 (S.D.W.Va. 2013).

E. Any Opinions Not Addressed in Case-Specific Expert Report

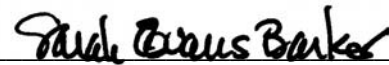
Finally, Defendants seek to have Dr. Margolis restricted from testifying as to any opinions not addressed in his case-specific expert report. Plaintiffs rejoin that Defendants' motion is premature and without a specific basis, arguing that, while they do not intend to introduce any opinions not disclosed in Dr. Margolis's report, he should be permitted to testify about the sources upon which he relied in forming his opinions. Clearly, Dr. Margolis is prohibited from offering opinions not properly disclosed in his expert reports. *See* Fed. R. Civ. P. 26(a)(2)(B)(i) ("The [expert] report must contain: ... a complete statement of all opinions the witness will express and the basis and reasons for them"). As for the admissibility of potential testimony regarding the sources upon which he relied in forming the opinions that *are* disclosed in his reports, we do not understand Defendants' motion to be directed at such testimony and, thus, we will not be drawn into making any speculative or advisory rulings. If such testimony is offered at trial, any objections to its admissibility can be raised at that time.

III. Conclusion

For the foregoing reasons, we GRANT IN PART and DENY IN PART Defendants' Motion to Exclude Specific-Causation Testimony of Michael Thomas Margolis, M.D. [Dkt. 86] as detailed in this Order. The parties are reminded that these are preliminary rulings as to the admissibility of anticipated trial evidence; thus, if other issues remain regarding Dr. Margolis's testimony, they can be raised and addressed in the context of the parties' motions in limine in advance of trial.

IT IS SO ORDERED.

Date: 11/2/2020



SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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